NOVARTIS AG
Form 6-K
January 19, 2012

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated January 19th 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: x Form 40-F: o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o **No**: x

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o **No**: x

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No**: x

Media Release | Medienmitteilung | Communiqué Aux Médias

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Sandoz initiates two more Phase III biosimilar trials, reinforcing long-term global leadership commitment

- *Phase III clinical study for filgrastim biosimilar (Neupogen®)*(1) *is expected to support expansion to the US market*
- *Phase III study for Sandoz pegfilgrastim (Neulasta®) represents next major step in Sandoz s global biosimilar development program*
- *Latest milestones further reinforce Sandoz s commitment to continued global biosimilar leadership, with a total of 8-10 molecules at various stages of development*

Holzkirchen, January 19, 2012 Sandoz announced today that it has initiated two milestone Phase III clinical trials one for biosimilar filgrastim (Amgen s Neupogen®) in the US market, the other for its global pegfilgrastim development program (Amgen s Neulasta®).

The filgrastim study is to evaluate the efficacy and safety of Sandoz s biosimilar filgrastim versus Neupogen® in breast cancer patients eligible for myelosuppressive chemotherapy treatment. It is expected to support extension of commercialization to the US, the largest global market for biologics. Sandoz s filgrastim biosimilar is already marketed under the brand name Zarzio® in more than 30 countries outside the United States.

The pegfilgrastim study, which is being conducted in breast cancer patients undergoing myelosuppressive chemotherapy treatment, represents the next major step in the Sandoz global biosimilar development program.

Sandoz is already the clear global leader in biosimilars overall and in each of our three marketed products, with approximately 50% total segment share in the highly regulated markets of North America, Europe, Japan and Australia , said Sandoz s global head, Jeff George. These two development milestones demonstrate that we also continue our efforts to make good on the longer-term promise of our leading pipeline.

In addition to Zarzio, Sandoz markets biosimilar somatropin (Omnitrope®) and epoetin alfa (Binocrit®) in countries across Europe and elsewhere. Omnitrope is also marketed in the US, under a different approval pathway.

Ameet Mallik, global head of Sandoz Biopharmaceuticals, added: The start of these two studies represents significant progress for our broad ongoing development program, which includes previously announced late-stage trials for biosimilar rituximab (Roche s Rituxan®). We will work to leverage our strong capabilities and our unique position within Novartis to drive the continued success of our biosimilar pipeline, with eight to 10 molecules at various stages of development.

As with all its biosimilar development programs, Sandoz has focused on using state-of-the-art analytical techniques and process development to produce molecules that are highly similar to their reference product, prior to launching tailored clinical programs to generate appropriate supportive data.

Zarzio is already the #1 filgrastim biosimilar worldwide, accepted in multiple markets as the first choice for primary prevention of febrile neutropenia (low white blood cell counts) and rapidly expanding global patient access to this essential biologic. Pegfilgrastim is a pegylated(2) form of recombinant human granulocyte-colony stimulating factor (G-CSF), or filgrastim, and Amgen s Neulasta® remains the best-selling G-CSF worldwide. It is the goal of Sandoz to create the #1 overall G-CSF franchise worldwide, with both its daily filgrastim and its once-per-cycle pegfilgrastim as the most-prescribed medicines in their respective areas.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as commitment, expected, longer-term promise, pipeline, plan, goal, or similar expressions, or by express or implied discussions regarding potential future marketing approvals of follow-on versions of filgrastim or pegfilgrastim or of other biosimilar products, or regarding potential future revenues from filgrastim or pegfilgrastim or other Sandoz biosimilar products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that filgrastim or pegfilgrastim will be submitted or approved for sale in any market, or at any particular time. Neither can there be any guarantee that Sandoz will succeed in developing and bringing to market any additional biosimilar products. Nor can there be any guarantee that filgrastim or pegfilgrastim or any other biosimilar products will achieve any particular levels of revenue in the future. In particular, management s expectations regarding such products could be affected by, among other things, unexpected clinical trial results including new clinical data and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; unexpected development difficulties; unexpected manufacturing difficulties; competition in general; government, industry and general public pricing pressures; unexpected patent litigation outcomes; the impact that the foregoing factors could have on the values attributed to the Group s assets and liabilities as recorded in the Group s consolidated balance sheet, and other risks and factors referred to in Novartis AG s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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About Sandoz

Sandoz, a Division of the Novartis Group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, affordable products that are no longer protected by patents. It has a portfolio of approximately 1000 compounds and sells its products in more than 130 countries. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments and hormone therapies. Sandoz develops, produces and markets these medicines along with pharmaceutical and biotechnological active substances. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany), Eon Labs (US), and EBEWE Pharma (Austria). In 2009, Sandoz employed approximately 23,000 people worldwide and posted sales of USD 7.5 billion.

For further information

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References:

(1) All registered trademarks named in this release are the property of the respective companies.

(2) Pegylation is the process of covalent attachment of polyethylene glycol polymer chains to another molecule, normally a drug or therapeutic protein.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: January 19th 2012

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial Reporting and Accounting